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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,243

12/20/2005

Ghisalberti Carlo

MARGI-0044

5778

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7590

09/05/2008

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.

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EXAMINER

WINTERBERG, NISSA M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

09/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/535,243

Applicant(s)

CARLO, GHISALBERTI

Examiner

Nissa M. Westerberg

Art Unit

1618

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 6, 8 - 19 is/are pending in the application.
- 4a) Of the above claim(s) 8 - 10, 15, 17, 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 6, 11 - 14, 16, 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI-108)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Applicants' arguments, filed June 4, 2008, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Election/Restrictions

1. Applicant has asked for clarification in regards to withdrawal of the restriction requirement but claims were withdrawn from consideration. The requirement for restriction between groups I and II was withdrawn. However, the species election requirement for the election of one hydroxypyridonone compound was not withdrawn. Therefore, the pending claims which do not read on the elected hydroxypyridonone species of deferiprone are withdrawn from consideration.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1 – 7, 11 – 14, 16 and 19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ghisalberti (WO 01/17497) in view of Murad (US 6,630,163). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed March 4, 2008 and those set forth below. Due to the amendments to the claims, this rejection is now applied to claims 1, 3 – 7, 11 – 14, 16 and 19.

Applicant argues that '497 deals only with the treatment of hyperpigmented skin which results from an excess of melanin and/or by hemosiderin deposits. Hyperpigmentation results in spots or area of dark color and is associated with sclerotherapy. Hemosiderin results in brown spots as evidenced by the definitions provided and that hemosiderinic spots do not arise from bleeding as alleged by the Examiner. '497 is silent as to the treatment of purpura, rosacea capillarities, rosacea, cutaneous vasculitis, itching purpura, purpura annularis telangiectodes, contact allergy capillaritis, traumatic skin hemorrhage or actinic purpura. In regards to the secondary reference, Murad et al., it does not teach or suggest the compounds of the instant invention as the teachings of the use of fruit extracts for dermatological conditions such as senile purpura, rosacea and hyperpigmentation adds nothing to the teachings of '497

and does not cure the deficiencies of the present invention. SMD are characterized by red spots and marks due to the perception of superficial blood flow and bleeding under the skin and therefore the pathologies caused by SMD are not similar to the hyperpigmentation disorders disclosed by '497.

These arguments are not found to be persuasive. '497 states "the formation of pigmentary spots may result from the combination of blood extravasation around the injection site" (p 3, ln 10 – 11) and that "hemoglobin is promptly bounded to the dermal and connective proteins, this forming hemosiderin deposits". Fluid leakage from inside the vascular system so that hemoglobin is exposed and binds to the dermal and connective proteins appears to "bleeding", although this bleeding does not result in the external appearance of blood. On p 5, Ghisalberti states "in our findings, substance such as 3-hydroxypyridone-derivatives represent the ideal depigmenting agents to be applied to hyperpigmented skin, as they show a combined activity towards melanin and/or hemosiderin deposits" (p 5, ln 8 – 10). The relative amounts of the melanin and hemosiderin may affect the outward appearance of the spots. In the specification of the instant application and the DermnetNZ references discussed in the previous office action, the causes/manifestations of these skin disorders is characterized by blood outside the blood vessels or bleeding under the skin. As it is a reaction the hemoglobin present in the blood with tissues that do not, under healthy conditions, come into contact with hemoglobin, results in the formation of hemosiderin, these condition will also result in the formation of hemosiderin, as stated by Applicant at p 1, ln 10 – 11 of the instant specification. '497 clearly teaches that deferiprone is an effective agent to be

topical applied for the treatment of spots that can contain hemosiderin (p 5, ln 8 – 10). Murad teaches that agents which are effective for the treatment of hyperpigmentation can also be used for the treatment of rosacea or purpura. Therefore, given the teachings of '497 that deferiprone can be used to treat hemosiderin deposits which may be associated with hyperpigmentation, the presence of hemosiderin in the clinical presentation of the claimed skin microcirculatory disorders and the teachings of Murad that agents which are effective for the treatment of hyperpigmentation are also suitable agents for the treatment of rosacea and purpura renders the instant claims obvious to an artisan of ordinary skill in the art.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW